New evidence for use of anti-inflammatory therapy for prevention of recurrent vascular events in stroke

May 15 2024

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In the international CONVINCE trial, presented today (15 May 2024) at the European Stroke Organization Conference (ESOC 2024), anti-inflammatory treatment with long-term colchicine did not reduce rates of recurrent stroke and cardiovascular events in patients with non-cardioembolic stroke in the primary intention-to-treat analysis.

Reduced event rates in secondary analyses, and in the subgroup of patients with coronary artery disease, support trials which reported benefit in coronary disease and may inform future secondary prevention trials in stroke.

Inflammation plays an important role in the pathophysiology of atherosclerosis. Over the past years, several trials have shown that anti-inflammatory treatment reduces recurrent vascular events in coronary artery disease, while no such evidence is available for stroke. Colchicine is an established drug to reduce inflammatory response and widely available at low cost.

CONVINCE was an international, randomized, open-label trial designed to test whether long-term colchicine (0.5 mg/day) in addition to standard of care reduces recurrent stroke or cardiovascular events in patients with non-cardioembolic ischemic stroke or high-risk transient ischemic attack (TIA).

The primary endpoint was a composite of first recurrent ischemic stroke, myocardial infarction, cardiac arrest or hospitalization for unstable angina. Over a period of almost six years and despite constraints imposed by the COVID-19 pandemic, 3,154 patients were randomized and followed for a median of 34 months.

In the intention-to-treat analysis, the primary endpoint occurred in 153
patients randomized to colchicine (9.8%) compared with 185 on usual care (11.8%), which translated into incidence rates of 3.32 versus 3.92/100 person-years. The adjusted hazard ratio was 0.84 (95% confidence interval 0.68-1.05, p=0.12).

Reduced levels of CRP in the colchicine group showed the anti-inflammatory effect of treatment with colchicine. In the pre-specified on-treatment analysis, as well as in the subgroup of patients with a history of coronary artery disease, significantly reduced rates of recurrent stroke or cardiovascular events were observed.

Professor Peter Kelly, the principal investigator of CONVINCE and Clinical Full Professor at University College Dublin School of Medicine and Mater Misericordiae University Hospital, said, "Although the primary analysis was neutral, the signals of benefit of colchicine on secondary analyses are in line with findings from previous trials and indicate the potential of colchicine in prevention after stroke.

"In CONVINCE, the COVID pandemic reduced the planned follow-up time, which led to under-powering for the primary analysis by 8%. Further trials are needed in all stroke subtypes, but with particular focus on patients with objective evidence of atherosclerosis."

In conclusion, although the primary endpoint was neutral, the results of CONVINCE support the hypothesis that long-term anti-inflammatory therapy with colchicine may reduce recurrent stroke and cardiovascular events specifically in stroke patients with atherosclerosis.
